510(K) SUMMARY

Date: March 31, 2000

Company: Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
N. Billerica, MA 01862

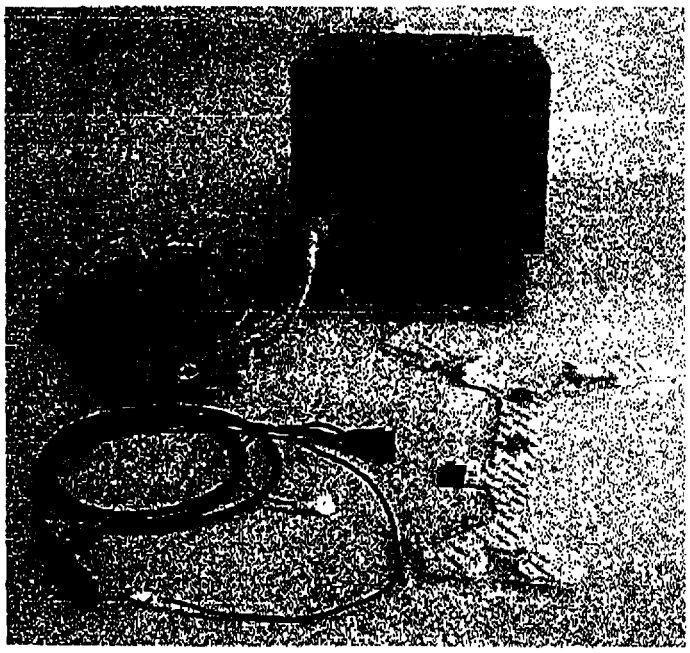
Contact: Dawn E. Frazer
Vice President
Regulatory Affairs & Quality Assurance
(978) 670-2422 x243
dfrazer@physiometrix.com

Subject Device: Model 4000 EEG Monitor with PSI

Classification: Class II, 21 CFR Part 882.1400, Electroencephalograph

Intended Use: The Physiometrix Model 4000 is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI™), a processed EEG parameter. The PSI™ index may be used as an aid in monitoring the effects of certain anesthetic agents.

Photograph:



Description: The PSA is an EEG monitor designed for use in the OR, ICU, EEG laboratory and for clinical research. It provides the ability to acquire and display real-time EEG waveforms, process the real time EEG data using digital signal processing techniques,

display the processed EEG data in several different formats, and archive the real-time or processed EEG data for future review.

The PSA4000 consists of three main components, the monitor, the amplifier and the archive media (optional). The device performs automatic self tests upon power up to ensure that the monitor and its components are functioning properly.

Monitor

The monitor provides signal processing and display capabilities for the 4 channels of real-time EEG data acquired from the preamplifier.

The monitor dimensions are 8.5" wide x 6.75" high x 20.75" deep. The color display area is 3.75" high x 5.2" wide. In addition to the display area, the front panel is configured with a number of soft and hard keys to allow for configuration of the display and data acquisition settings.

The processor is a PC-based CPU that processes the EEG data, calculates the processed parameters and displays the real-time EEG data and processed data. Processed parameters include Electromyograph (EMG), Artifact (ART), Suppression Ratio (SR), and the Patient State Index (PSI).

Patient Module

The patient module is an electrically isolated, low noise, high gain, analog to digital signal converter that can process up to 4 channels of real-time data. The preamplifier dimensions are 4.25" wide x 1.75" thick x 5.5" high. The patient module includes a clamp that can be used to secure the unit. The clamp can accommodate a pole of up to 1" in diameter. The preamplifier is connected to the patient and monitor through flexible, shielded cabling.

Archive Media (optional)

The PSA4000 has an optional PCMCIA slot. When a PCMCIA card is detected on start up of the monitor, data will be automatically stored on the PCMCIA Hard Disk Drive.

Predicate Device: K963644, Aspect Medical Systems EEG Monitors, A-1000 and A-1050
K974496 Aspect Medical Systems A-2000 EEG Monitor with BIS

Similarities: The PSA4000 is similar to the predicate devices in the following ways:

a. Both systems are EEG monitors.
b. Both systems provide a variety of processed parameters.
c. Both systems include an index that may be used to monitor the effect of certain anesthetics.
d. Both conduct self tests at start up to assure that the device is operating.
e. Both systems have two main components, a monitor and a preamplifier.

Differences: The PSA4000 is different from the predicate device in the following ways:

a. The PSA4000 has a PCMCIA option while the predicate device has a printer option.
b. The PSA4000 does not include the processed parameter, Density Spectral Array (DSA).

c. The PSA4000 incorporates a larger screen than the A-2000.

d. The PSA4000 includes a high resolution color monitor while the predicate device has a monochrome monitor.

e. The PSA4000 displays four channels of EEG while the predicate device displays either one or two channels of EEG.

Test Results:

The following tests have been conducted in order to verify and validate the device: software, mechanical and electrical validation testing, EMC testing and clinical evaluation.

The PSA4000 System has been testing in accordance with the following standards.

- UL 2601
- CSA 22.2 No. 601-1
- IEC601-1
- IEC601-2-26
- FDA Reviewer Guidance for Pre-market Notification Submissions, Section 7, Electromagnetic Compatibility dated November 1993.

The test results are all positive and indicate that the device meets product requirements and satisfies customer needs and expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2000

Ms. Dawn E. Frazer
Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
N. Billerica, MA 01862

Re: K001069
Model 4000 EEG Monitor with PSI
Regulatory Class: II (two)
Product Code: 84 GWQ
Dated: March 31, 2000
Received: April 3, 2000

Dear Ms. Frazer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant:	Physiometrix, Inc.
510(k) Number (if known)	Not assigned K001069
Device Name	Model 4000 EEG Monitor with PSI
Indications For Use	The Physiometrix Model 4000 is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI™), a processed EEG parameter. The PSI™ index may be used as an aid in monitoring the effects of certain anesthetic agents.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

Division of Cardiovascular & Respiratory Devices
510(k) Number K001069

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)